

REMARKS

Claims 1-20 and 68-79 are pending in the present application. In the Non-Final Office Action mailed September 13, 2007, claims 1-20 and 68-79 were rejected. Reconsideration of the present application in view of the remarks that follow is respectfully requested.

Claim Rejections

Claims 1-20 and 68-79 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2004/0147928 to Landry et al. (hereafter "Landry") in view of U.S. Patent No. 6,517,565 to Whitman et al. (hereafter "Whitman"). As an initial matter, Applicants reserve the right to remove Landry with an affidavit under 37 C.F.R. §1.131 in this and any continuing applications. However, assuming only *arguendo* that Landry may be asserted with respect to the present application, it is believed that claims 1-5, 10-14, 19 and 20 are patentable over its combination with Whitman, as will be explained in the following comments.

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. See, MPEP §2141. From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness. Additionally, the Supreme Court in the recent decision of KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385, 127 S.Ct 1727, 167 L.Ed.2d 705 (U.S. 2007), citing In Re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), stated:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

KSR, 82 USPQ2d at 1396. For the reasons that follow, it is respectfully submitted that the Office Action lacks the required cogent rationale for modifying Landry in view of Whitman to arrive at the invention of claims 1-20 and 68-79.

As indicated above, Graham requires that the scope and content of the prior art are to be determined. Pursuant to the obligation to determine the appropriate scope of prior art, one subheading of the *Manual of Patent Examining Procedure* (MPEP) notes that to rely on a reference under 35 U.S.C. §103, it must be analogous prior art. See, MPEP §2141.01(a). More particularly, “[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” See, MPEP §2141.01(a) citing In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Applicant respectfully submits that Whitman is clearly not analogous art.

All of the pending claims are generally directed to a device for guiding an implant to a location adjacent a bone anchor. As might be expected, the primary reference applied by the Office Action (Landry) is entitled “Spinal Stabilization System Using Flexible Members.” In contrast, the secondary reference (Whitman) has nothing to do with a device for guiding an implant to a location adjacent a bone anchor. Instead, Whitman discloses at, column 1, lines 15-21:

The present invention relates generally to electromechanical devices for use with surgical instruments and more specifically to a carriage assembly for controlling a steering wire steering mechanism within a flexible shaft, suitable for use with an electromechanical driver assembly by which surgical attachments incorporating anastomosing, stapling, and resecting tools may be remotely actuated.

Whitman also discloses, at column 4, lines 9-17:

Therefore, it is a principal object of the present invention to provide an instrument for cutting, anastomosing, and stapling, for use in gastrointestinal surgery, which reduces the waste of resources by permitting the reuse of portions thereof. It is further an object of the present invention to provide an instrument assembly which reduces the requirements for the surgeon to manually actuate different components and mechanisms.

Likewise, Applicants have found no mention in Whitman of any device for guiding an implant to a location adjacent a bone anchor. Consequently, Whitman is clearly not in the same field of endeavor as the subject application, nor has the Office Action provided any evidence of such.

It must also be considered whether Whitman is reasonably pertinent to the particular problem of the subject application. The standard for making this determination is:

A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the purpose of the both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

In re Clay, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992). Whitman does not deal with any problem having a logical connection to the present invention. Particularly, Whitman addresses problems associated with steering surgical attachments that are attached to an electromechanical driver assembly for performing anastomosing, stapling, and resecting functions during gastrointestinal surgery. Moreover, Whitman discloses no purpose that reasonably relates its instrument for use in solving the problem addressed by the present invention. The present invention provides a guide member for a guiding an implant to a location adjacent a bone anchor to facilitate alignment of the implant with the bone anchor in a patient's body. Whitman's purpose, *inter alia*, is to provide a single steerable instrument for performing several tasks during gastrointestinal surgery, and is by no means directed to guiding anything along the instrument. Since the purpose of the instrument in Whitman addresses problems which are so unrelated to the problem addressed by the guide members of the present invention, there is no motivation to consider it. Thus, Whitman is nonanalogous art that cannot be fairly used in the asserted obviousness rejection.

In addition to the foregoing, further reasons undermine the obviousness rejections set forth in the Office Action. For example, independent claim 1 recites "wherein said guiding portion is flexible and positionable between an untaut configuration and a taut configuration as the implant is guided therealong" while claim 10 recites "wherein said guiding portion is structured to move between a loose condition and a taut condition." The Office Action asserts, in the sentence spanning pages 2-3, that Whitman discloses "a shaft that is flexible and positionable between an untaut configuration and a taut configuration." Despite the dissimilarity of Whitman, the Office Action asserts that those skilled in the art would have modified Landry in view of Whitman "to allow the operator to steer the flexible shaft portion as desired." See, Office Action, page 3, lines 5-6. The Office Action also asserts, on page 4, lines 5-6, that Whitman discloses "a guiding portion that is flexible and positionable between an untaut configuration and taut configuration as the implant is guided therealong."

It is well settled that, to establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." See, (MPEP) §2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As an initial matter, Whitman does not disclose a shaft and/or a guiding portion that is positionable between an untaut and taut configuration as an implant is guided therealong, as suggested by the Office Action. Indeed, the portion of Whitman cited by the Office Action (column 5, lines 4-27) describes steering wires 126, 140 which may be positioned between a taut and limp configuration to steer surgical attachments. See also e.g., Whitman, column 11, lines 32-39. Steering wires 126, 140 extend along a flexible shaft 122 and are coupled to the tip of flexible shaft 122. In this configuration, a user may rotate trackball 124 and initiate actuation of steering motors 130, thereby rotating pulleys 160 to pull on steering wires 126, 140 and correspondingly turn the tip of flexible shaft 122. See e.g., Whitman, column 11, lines 23-49; column 12, lines 55-61; and Figures 2a and 3. After reviewing Whitman and understanding the purpose of steering wires 126, 140, Applicants respectfully submit that they do not serve as a guiding portion or to guide anything therealong. In fact, steering wires 126, 140 are positioned within shaft 122, eliminating the possibility of anything being guided therealong. Moreover, Whitman also fails to disclose that shaft 122 is a guiding portion or that anything is guided therealong.

Accordingly, even if guide member 100 of Landry were modified as suggested by the Office Action, it would fail to include all the limitations of claims 1 and 10. In particular, it would not include "a guiding portion that is flexible and positionable between an untaut configuration and a taut configuration as the implant is guided therealong," as recited by claim 1. Nor would it include a "guiding portion [is] structured to move between a loose condition and a taut condition," as recited by claim 10.

As a further matter, Applicants submit that those skilled in the art would not modify the guide member 100 of Landry as suggested by the Office Action. The motivation promoted by the Office Action for modifying guide member 100 of Landry in view of Whitman is that it would allow the operator to steer the flexible shaft portion as desired. To facilitate steering of guide member 100, the steering wires, pulleys, steering motors and carriage assembly of Whitman would somehow have to be incorporated into guide member 100. Whitman clearly does not disclose that the carriage assembly, including the steering wires, pulleys, and steering motors, is configured for anything to be guided thereover. As a corollary, if guide member 100 were modified to include these features, it would no longer be useful for its intended purposes (i.e., as a member for guiding implants toward a bone anchor) and consequently, those skilled in the art would not make such a modification. As a further matter, the instrument of Whitman is structured to steer surgical attachments through the confined, and at times enclosed, spaces of the gastrointestinal tract, including for example, the bowel and colon. See e.g., Whitman, column 16, lines 3-11. To the contrary, in Landry the threaded members 108 are exposed through incisions in the skin of the patient to facilitate coupling of guide members 100 thereto. See e.g., Landry, paragraph [0056]. Accordingly, there is no need for modifying guide member 100 to allow an operator to steer it, and doing so would increase manufacturing costs and complexity without providing any advantageous result. Therefore, those skilled in the art would not modify guide member 100 in such a manner.

Furthermore, when considering Landry in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention (see MPEP §2141.02, citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)), those having skill in the art would not modify guide member 100 to arrive at the invention of claims 1 and 10; i.e., to include a guiding portion positionable between an untaut and taut configuration. For

example, guide member 100 includes threads 104 which engage with threads of section 130 of threaded member 108. See e.g., Landry, Figure 6 and paragraph [0064], lines 7-10. Additionally, guide member 100 is used for guiding and placing a driver member 134 into communication with threaded member 108. See e.g., Landry, paragraph [0070], lines 8-11. If guide member 100 were positionable in an untaut configuration, rotating guide member 100 to threadingly engage threads 104 with member 108 would not be possible with the disclosed configuration of guide member 100 since the torque required to engage threads 104 by rotating the proximal portion of guide member 100 would not be effective to create the threaded engagement, particularly considering that section 130 is positioned entirely internally relative to the end of threaded member 108.

In addition, positioning driver member 134 over guide member 100 in an untaut configuration would not be possible unless a constant tension were applied to guide member 100 during the guidance of driver member 134 thereover. However, when considering the configuration of driver member 134, it is clear that a constant tension could not be applied to guide member 100 as driver member 134 is placed thereover. Even further, Landry discloses guide member 100 may be positioned through driver member 134 to engage with threaded member 108. See, Landry, paragraph [0100], lines 10-13. However, if guide member 100 included an untaut configuration, it would also be extremely impractical, if not impossible, to engage guide member 100 with section 130 of threaded member 108 as guide member 100 is positioned through both the long passage of driver member 134 and passage 122. Accordingly, those having skill in the art would be led away from modifying guide member 100 to arrive at the inventions of claims 1 and 10.

In view of the foregoing, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to independent claims 1 and 10. Withdrawal of this rejection and allowance of these claims are respectfully requested. Each of claims 2-9 depends from base claim 1 or an intervening claim and is submitted as patentable for at least the reasons supporting the patentability of claim 1. However, additional reasons support the patentability of these claims as well.

For example, claim 7 recites "wherein said distal extensions each include an engagement portion extending therefrom engageable with the bone anchor." The Office Action recognizes

that Landry fails to disclose any engagement portion extending from a distal extension. See e.g., Office Action, page 3. However, it asserts that Whitman discloses these features. Whitman discloses that distal ends 138a, 138b of drive shafts 136a, 136b may engage with an attachment. More specifically, Whitman discloses, at column 13, lines 28-38:

[T]he distal tips 138a, 138b of the flexible drive shafts 136a, 136b must have a conformation which permits the continued translation of torque. In the shown embodiment, this coupling is achieved by a geometric fitting. More precisely, the distal tips of the flexible drive shafts are hexagonal, and thereby fit into hexagonal recesses in the coupling interface of the attachment. In certain embodiments of the electromechanical driver assembly, the attachment and the distal end of the flexible drive shaft should include a collar, or other aligning means, for facilitating the fitting of the attachment onto the distal end of the flexible drive shaft.

Of the all the engagement arrangements disclosed by Whitman, none includes distal extensions that each includes an engagement portion extending therefrom engageable with a bone anchor. Since the combination of Landry and Whitman fails to disclose all the elements of claim 7, claim 7 can not be rendered obvious thereby. Moreover, if the Office Action maintains this rejection, Applicants respectfully request citation(s) to the portion(s) of Whitman where these features are disclosed. Claim 8 recites that "said engagement portions each project laterally from said respective distal extension" while claim 9 recites that "said distal extensions are deflectable toward one another for insertion into the bone anchor and biased toward a pre-insertion orientation to facilitate said engagement portions engaging the bone anchor." The features of claims 8 and 9 are also not disclosed by the cited references. Accordingly, these claims are also further submitted as patentable.

Each of claims 11-20 depends from base claim 10 or an intervening claim and is submitted as patentable for at least the reasons supporting the patentability of claim 10. Claims 16, 17 and 18 recite subject matter similar to that of claims 7, 8 and 9, respectively, and are further submitted as patentable for the same reasons submitted above with respect to claims 7-9.

Independent claim 68 also stands rejected as being unpatentable over Landry in view of Whitman. Claim 68 recites, among other features and elements, "said connecting portion includes a body and a pair of extensions extending distally from said body, said distal extensions each include an engagement portion extending therefrom releasably engageable with the bone

anchor.” The Office Action asserts that Landry discloses all the features of claim 68 “except for a connecting portion including a pair of extensions to releasably engage with the bone anchor.” See, Office Action, page 3, lines 8-9. The Office Action further asserts that it would have been obvious to modify Landry in view of the teachings of Whitman in order “to releasably fasten and secure an anchor.” See, Office Action, page 3, lines 14-15.

For at least the reasons submitted above with respect to claim 7, the combination of Landry and Whitman fails to disclose distal extensions that each includes an engagement portion extending therefrom releasably engageable with the bone anchor, as recited by claim 68. As a corollary, claim 68 cannot be rendered obvious by this combination of references. Additionally, when considering the entire scope and content of Landry, one of ordinary skill in the art would have no reason to modify Landry to arrive at the invention of claim 68. As discussed above, Landry teaches that guide member 100 is engageable with section 130 which is positioned entirely within passage 122 of threaded member 108. Likewise, modifying guide member 100 to include “a pair of extensions extending distally from said body, said distal extensions each include an engagement portion extending therefrom releasably engageable with the bone anchor” would prevent guide member 100 from passing through the elongated and narrow passage 122 to engage with section 130. Furthermore, Landry teaches that guide member 100 is structured to pass through the elongated and narrow passage of driver member 134 to engage with threaded member 108. It is respectfully submitted that modifying Landry to arrive at the invention of claim 68 would prevent guide member 100 from passing through driver member 134 into engagement with threaded member 108.

Furthermore, Landry already teaches releasable engagement of guide member 100 with member 108 via a low profile threaded connection or other connection that is internal to the member 108. The Office Action asserts the reason for modifying Landry with Whitman is in order to releasably fasten and secure an anchor. However, Landry already solves this problem with the releasable connection arrangement between guide member 100 and member 108. One of ordinary skill in the art would have no reason to further modify Landry to include the coupling arrangement of Whitman or the features of claim 68 when the device of Landry already solves the problem asserted to provide the reason for its modification.

For at least these reasons, it is respectfully submitted that a *prima facie* case of obviousness has not been established. Accordingly, claim 68 is submitted as patentable over the combination of Landry and Whitman. Each of claims 69-73 depends from base claim 68 or an intervening claim and is submitted as patentable for at least the reasons supporting the patentability of claim 68. Additionally, claims 71 and 72 are directed to subject matter similar to that of claims 8 and 9, respectively, and are further submitted as patentable for at least the reasons discussed above with respect to claims 8 and 9. Claim 73 recites "wherein said guiding portion is structured to move between a loose condition and a taut condition." For the same reasons submitted above with respect to claims 1 and 10, a *prima facie* case of obviousness has also not been established with respect to claim 73. Accordingly, allowance of claims 68-73 is respectfully requested.

Independent claim 74 has also been rejected as being unpatentable over Landry in view of Whitman. Independent claim 74 recites, among other features and elements, "said connecting portion includes a body and a pair of extensions extending distally from said body, said distal extensions each include an engagement portion extending therefrom releasably engageable with the bone anchor." For at least the reasons submitted above with respect to claim 7, the combination of Landry and Whitman fails to disclose distal extensions that each includes an engagement portion extending therefrom releasably engageable with the bone anchor, as recited by claim 74. Furthermore, as suggested above with respect to independent claim 68, those skilled in the art would not modify the guide member 100 of Landry as suggested by the Office Action or to arrive at the invention of claim 74. Accordingly, claim 74 is submitted as patentable over the combination of Landry and Whitman. Each of claims 75-79 depend from base claim 74 or an intervening claim and is submitted as patentable for at least the reasons supporting the patentability of claim 74. Additionally, claims 77 and 78 are directed to subject matter similar to that of claims 8 and 9, respectively, and are further submitted as patentable for at least the reasons discussed above with respect to those claims. Claim 79 recites "wherein said guiding portion is structured for positioning between a loose condition and a taut condition." For the same reasons submitted above with respect to claims 1 and 10, a *prima facie* case of obviousness has also not been established with respect to claim 79. Accordingly, allowance of claims 74-79 is respectfully requested.

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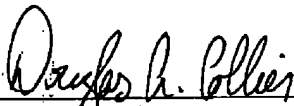
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CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 1-20 and 68-79.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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